

What would I find in your TMF?

Top 10 problems

and the best practices to avoid them



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20 May 2022
0.2 20220505

Disclaimer

These views are my own,
and not necessarily those of my employer,
past, present or future.

Second Disclaimer

These are common *almost universal* issues.

Please do not assume I am talking about a particular situation, sponsor, CRO or trial.

I have seen each of these *dozens* of times in dozens of different circumstances.

1) Ethics is incomplete





Sometimes very incomplete

Review the dialogue



Artifact Number	Artifact Name	Subartifact	Date	Detail
04.01.01	Ethics Submission	Cover Letter	05 Jun 2018	Initial Submission. Protocol V1.0 17Apr2018. Main ICF V1.1.0 24May2018.
04.01.01	Ethics Submission	Submission	05 Jun 2018	Initial Submission. Protocol V1.0 17Apr2018. Main ICF V1.1.0 24May2018.
04.01.01	Ethics Submission	Acknowledgement of Receipt	06 Jun 2018	Initial Submission 05Jun2018.
04.01.01	Ethics Submission	Query	25 Jun 2018	
04.01.01	Ethics Submission	Query Response	03 Jul 2018	Query 25Jun2018. Main ICF V1.2.0 02Jul2018.
04.01.02	Ethics Decision	Approval	03 Aug 2018	Initial Approval. Protocol V1.0 17Apr2018. Main ICF V1.2.0 02Jul2018.
04.01.01	Ethics Submission	Cover Letter	02 Feb 2019	Substantial Amendment 1. Protocol V2.0 26Jan2019. Main ICF V2.1.0. 27Jan2019.
04.01.01	Ethics Submission	Submission	02 Feb 2019	Substantial Amendment 1. Protocol V2.0 26Jan2019. Main ICF V2.1.0. 27Jan2019.
04.01.02	Ethics Decision	Approval	04 Mar 2019	Substantial Amendment 1. Protocol V2.0 26Jan2019. Main ICF V2.1.0. 27Jan2019.
04.01.01	Ethics Submission	Notification	21 Apr 2019	IB Ed.17 20Apr2019.
04.01.01	Ethics Submission	Acknowledgement of Receipt	21 Apr 2019	Notification 21Apr2019
04.01.01	Ethics Submission	Cover Letter	24 Jan 2020	Substantial Amendment 2. Main ICF V2.2.0. 23Jan2020. Pregnancy ICF V1.1.0. 16Jan2020
04.01.01	Ethics Submission	Submission	24 Jan 2020	Substantial Amendment 2. Main ICF V2.2.0. 23Jan2020. Pregnancy ICF V1.1.0. 16Jan2020
04.01.01	Ethics Submission	Acknowledgement of Receipt	24 Jan 2020	Submission 24Jan2020
04.01.02	Ethics Decision	Approval	26 Feb 2020	Substantial Amendment 2. Main ICF V2.2.0. 23Jan2020. Pregnancy ICF V1.1.0. 16Jan2020

05 Jun 2018	Cover Letter				
05 Jun 2018	Submission	06 Jun 2018	AoR	25 Jun 2018	Query
03 Jul 2018	Query Response			03 Aug 2018	Approval
02 Feb 2019	Cover Letter				
02 Feb 2019	Submission			04 Mar 2019	Approval
21 Apr 2019	Notification	21 Apr 2019	AoR		
24 Jan 2020	Cover Letter				
24 Jan 2020	Submission	24 Jan 2020	AoR	26 Feb 2020	Approval

Things missing from this simplified example:

- There would be more things in the initial submission.
- Expiry Date for the Approval.
- Metadata field for 'Initial'.
- Submission Package QC & Approval Forms.
- Substantiality Assessment Forms.

2) Regs is incomplete

Exactly the same as for ethics



3) Site stops suddenly

We need more documents



WEEK
2022



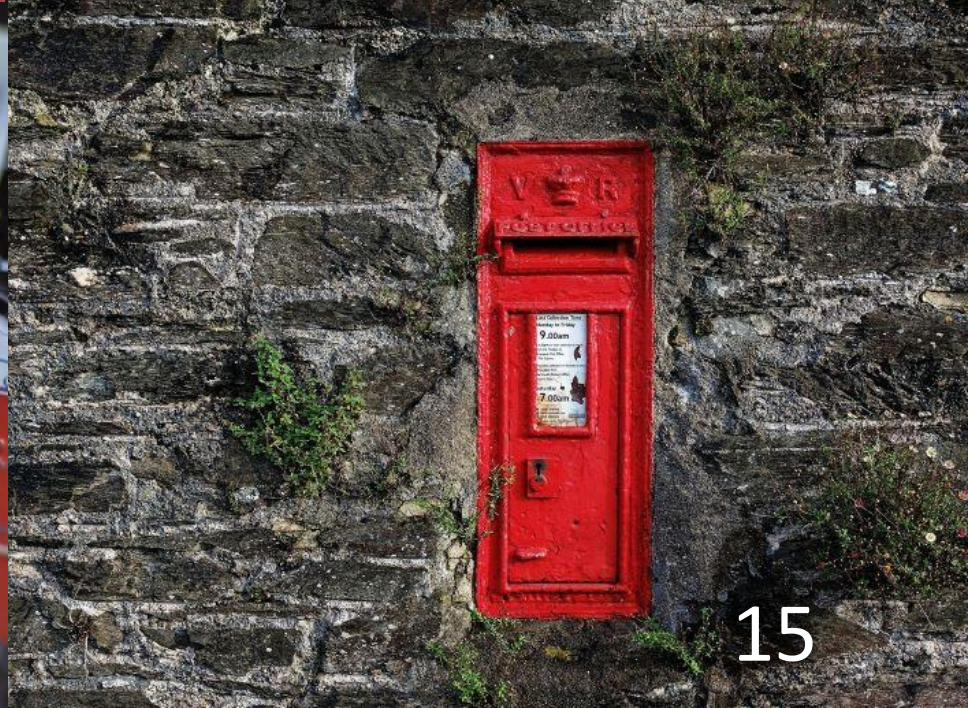
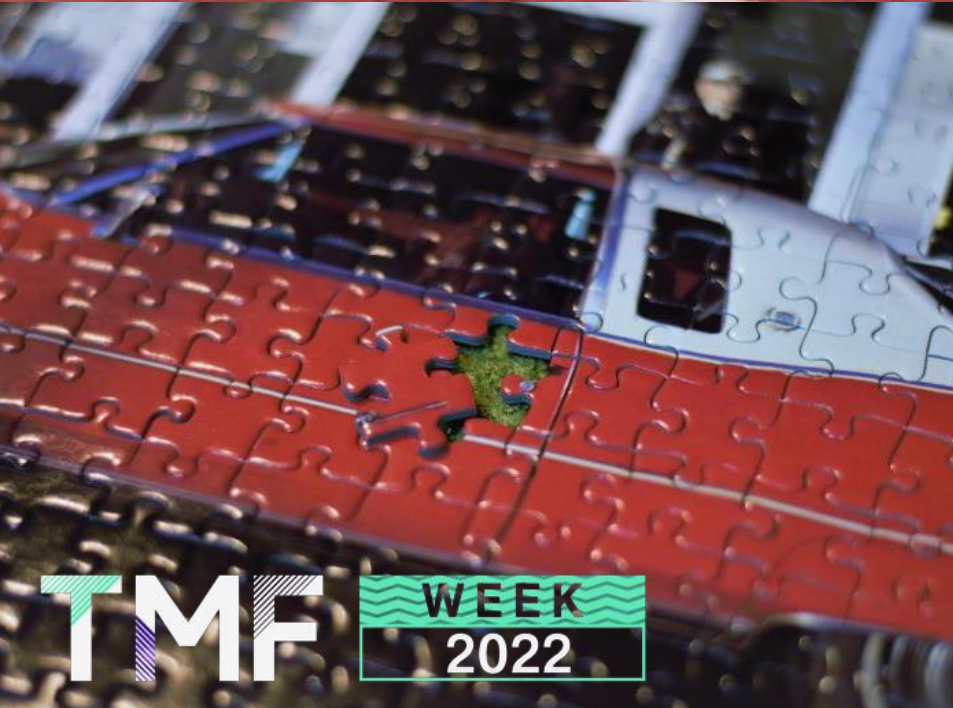
4) Filenotes pointing at problems



- 29 DOWN STARTING LOOP TO BRANCH
- 30 DOWN STARTING LOOP TO BRANCH
- 31 DOWN BRANCH TO LOOP
- 32 DOWN STARTING MAIN TO BRANCH
- 33 DOWN STARTING MAIN
- 34 DOWN MAIN SECOND HOME
- 35 DOWN MAIN HOME



5) Central ethics vs local ethics



6) Site Delegation Log with awful corrections



997243-1

TMF

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8) Gaps in a sequence





TMF

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H) Inconsistency

ICF Type	<input type="text"/>
Language	Main
Version	Parent
	Child Assent
	Sampling
Tags	Imaging
Lifecycle State Stage ID	Pharmacogenetics
Lifecycle Stage	Data Privacy
Document Link	Withdrawal
	Pregnancy
	Pregnant Partner

9) Autopaginated documents & broken tables


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X	NO	X	NO	D	Per content		X
X	NO	X	NO	D	Per content		X
X	NO	X	NO	D	14	Secure Regulatory Approvals	X
X	NO	X	NO	D	13	Secure Ethical Approvals	X
X	X	X	X	M	13	Secure Ethical Approvals	
X	X	X	X	M	13	Secure Ethical Approvals	
X	X	X	X	M	13	Secure Ethical Approvals	
X	X	X	X	M	13	Secure Ethical Approvals	
X	X	X	X	M	15	Secure Other Approvals	

Technical Wizardry

Excel is different to Word. In Word if you want a bigger page you can define any custom size. In Excel to do the same thing you need a printer driver.

I recommend:



Canon Pro 4100 SR 44" 12 Colour Printer
3869C003AA

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TMF Reference Model		TMF 2.0.0.0	Version 2.2.1	01/04/21
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TMF Reference Model	TMF 2.0.0.0	Version	Date	Description	Status	Priority	TMF 2.0.0.0		TMF 2.0.0.0		TMF 2.0.0.0		TMF 2.0.0.0		TMF 2.0.0.0		TMF 2.0.0.0		TMF 2.0.0.0		
							TMF 2.0.0.0	TMF 2.0.0.0	TMF 2.0.0.0	TMF 2.0.0.0	TMF 2.0.0.0	TMF 2.0.0.0	TMF 2.0.0.0	TMF 2.0.0.0	TMF 2.0.0.0	TMF 2.0.0.0	TMF 2.0.0.0	TMF 2.0.0.0	TMF 2.0.0.0	TMF 2.0.0.0	TMF 2.0.0.0
1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6
1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7
1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8
1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9
1.10	1.10	1.10	1.10	1.10	1.10	1.10	1.10	1.10	1.10	1.10	1.10	1.10	1.10	1.10	1.10	1.10	1.10	1.10	1.10	1.10	1.10
1.11	1.11	1.11	1.11	1.11	1.11	1.11	1.11	1.11	1.11	1.11	1.11	1.11	1.11	1.11	1.11	1.11	1.11	1.11	1.11	1.11	1.11
1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12
1.13	1.13	1.13	1.13	1.13	1.13	1.13	1.13	1.13	1.13	1.13	1.13	1.13	1.13	1.13	1.13	1.13	1.13	1.13	1.13	1.13	1.13
1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14
1.15	1.15	1.15	1.15	1.15	1.15	1.15	1.15	1.15	1.15	1.15	1.15	1.15	1.15	1.15	1.15	1.15	1.15	1.15	1.15	1.15	1.15
1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16
1.17	1.17	1.17	1.17	1.17	1.17	1.17	1.17	1.17	1.17	1.17	1.17	1.17	1.17	1.17	1.17	1.17	1.17	1.17	1.17	1.17	1.17
1.18	1.18	1.18	1.18	1.18	1.18	1.18	1.18	1.18	1.18	1.18	1.18	1.18	1.18	1.18	1.18	1.18	1.18	1.18	1.18	1.18	1.18
1.19	1.19	1.19	1.19	1.19	1.19	1.19	1.19	1.19	1.19	1.19	1.19	1.19	1.19	1.19	1.19	1.19	1.19	1.19	1.19	1.19	1.19
1.20	1.20	1.20	1.20	1.20	1.20	1.20	1.20	1.20	1.20	1.20	1.20	1.20	1.20	1.20	1.20	1.20	1.20	1.20	1.20	1.20	1.20

To document which standard operating procedures were in effect for the duration of the trial and the trial. To include sponsor and third party the SOPs themselves. May include SOP study-specific deviation from a named SOP



10) Hidden treasure



Bonus: versioning

1,2,3,4,5,6,7,8,etc

1.0, 2.0, 3.0 etc for final versions

0.01, 3.02 etc for drafts

1.1.1 for documents at all three levels

Have you got widely shared written instructions and understanding on how to version control documents?

